EDUCATION FOR THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS IN THE RESEARCH & DEVELOPMENT SERVICE

1. **PURPOSE:** To establish a service level policy that identifies the individuals required to complete educational requirements in the protection of human research participants and the educational programs that meet these requirements. This policy will help to ensure the protection of all human research participants and promote ethical standards of human research performed at the Portland VA Medical Center (PVAMC).

2. **POLICY:** All individuals responsible for the protection of human subjects in research at the PVAMC are required to complete an education program, consistent with the requirements of the Department of Veterans Affairs regulations, in the protection of human research participants. This includes, but is not limited to the: Associate Chief of Staff, R&D; Administrative Officer, R&D; Research & Development Committee (R&D) Members and Alternates; Institutional Review Board (IRB) Members and Alternates; IRB Coordinators; Research Assurance & Compliance Coordinator (RACC); all Principal Investigators involved in human subjects research; and all Co-Principal Investigators, Co-Investigators, and all other research and/or medical personnel participating on a PVAMC IRB approved research project. This includes individuals who handle identifiable VA patient human biological specimens, identifiable VA patient data, and/or have direct research related contact with VA patients participating in research. The education requirement, consistent with VA regulations, is met through successful completion of one of the following options:
   a. (1) VHA Overview of Good Clinical Practice and Human Subjects Protection module **and**
      (2) PVAMC Education in the Protection of Human Research Participants training module; or
   b. (1) National Cancer Institute's (NCI) Human Participants Protection Education for Research Teams module,
      (2) PVAMC Education in the Protection of Human Research Participants training module, **and**
      (3) VHA Good Clinical Practice (GCP) module; or
   c. (1) University of Rochester Medical Center's manual Protecting Study Volunteers in Research post-test,
      (2) PVAMC Education in the Protection of Human Research Participants training module, **and**
      (3) VHA GCP module; or
   d. (1) University of Miami's Collaborative IRB Training Initiative module **and**
      (2) VHA GCP module.

   Once a, b, c, or d (from above) is completed, an individual is considered "certified" to participate in research with human subjects at the PVAMC. Re-certification is required annually, specifically on a 365-day basis. The above stated programs encompass the Veterans Health Administration (VHA) Office of Research & Development (ORD) educational requirements. All involved personnel must complete and submit documentation of this educational requirement prior to final study approval by the IRB and prior to participating on IRB approved research projects. The Research & Development (R&D) Service Office will monitor completion and renewal of educational requirements. This policy allows only those individuals with the appropriate training to be involved with the human research participants.

3. **RESPONSIBILITIES:**

   a. The **Associate Chief of Staff of Research & Development** is responsible for:
      (1) Developing and managing policies and procedures that ensure compliance with the educational requirements of the R&D Service.
      (2) Successfully fulfilling the educational requirement in the protection of human research participants.

(3) Completing the education requirement in the protection of human subjects in research training annually.

b. The **Administrative Officer of Research & Development** is responsible for:
   (1) Implementing the educational requirement policy through the administrative office of R&D Service.
   (2) Successfully fulfilling the educational requirement in the protection of human research participants.
   (3) Completing the education requirement in the protection of human subjects in research training annually.

c. The **Research & Development Committee** (R&D) is responsible for:
   (1) Successfully fulfilling the educational requirement in the protection of human research participants.
   (2) Completing the education requirement in the protection of human subjects in research training annually.

d. **The Institutional Review Board** (IRB) **Members** are responsible for:
   (1) Successfully fulfilling the educational requirement in the protection of human research participants.
   (2) Completing the education requirement in the protection of human subjects in research training annually.
   (3) Completing other education requirements as set forth by the IRB Chair(s).

e. The **Institutional Review Board Coordinators** are responsible for:
   (1) Successfully fulfilling the educational requirement in the protection of human research participants.
   (2) Completing the education requirement in the protection of human subjects in research training annually.
   (3) Verifying that all Principal Investigators submitting new and continuing reviews of protocols involving human research participants, human biological specimens and/or human data have successfully completed the required training prior to final IRB study approval.
   (4) Verifying that all Co-Principal Investigators, Co-Investigators, and all other research and/or medical personnel participating on an IRB approved research project have successfully completed the required training prior to final IRB study approval. This includes individuals who handle identifiable VA patient human biological specimens, identifiable VA patient data, and/or have direct research related contact with VA patients participating in research.
   (5) Forwarding to the IRB only research projects involving human research for initial review in which all necessary personnel have completed the appropriate education in the protection of human research participants.
   (6) Alerting the IRB as to the possible need for suspending research projects involving human research in which necessary personnel have not completed the appropriate education in the protection of human research participants.

f. The **Research Assurance and Compliance Coordinator** is responsible for:
   (1) Successfully fulfilling the educational requirement in the protection of human research participants.
   (2) Maintaining and monitoring all required individuals', involved in human subjects research, educational requirements for the Protection of Human Research Participants in the Personnel database.
   (3) Notifying Investigators and staff when educational requirements in the protection of human research participants need to be renewed.

(4) Completing the education requirement in the protection of human subjects in research training annually.

g. **Principal Investigators**
Principal Investigators (VA employees or appointees (including those serving without compensation)) who have current active IRB approved research projects for use of human research participants, human biological specimens and/or human data are responsible for:
(1) Successfully fulfilling the educational requirement in the protection of human research participants.
(2) As necessary, completing the above educational requirements prior to initial review of human research project submission to the IRB.
(3) Submitting documentation of successful completion of educational requirements prior to initial review of research project submission to the IRB, if not previously completed.
(4) Alerting the IRB to changes of study personnel.
(5) Ensuring all required individuals involved in their studies have completed the above required protection of human research participants training.
(6) Completing the education requirement in the protection of human subjects in research training annually.

h. **Research Employees and other Medical Center Staff** participating on an IRB approved research project must successfully complete the required training prior to final IRB study approval are responsible for:
Note: This includes individuals who handle identifiable VA patient human biological specimens, identifiable VA patient data, and/or have direct research related contact with VA patients participating in research.
(1) Successfully fulfilling the educational requirement in the protection of human research participants.
(2) Submitting documentation of successful completion of the above educational requirements to the Research Service prior to human research participant contact.
(3) Completing the education requirement in the protection of human subjects in research training annually.

4. PROCEDURES:

a. **All individuals responsible for completing the education requirements for the Protection of Human Subject Participants must adhere to the following procedures:**

(1) Successfully complete, one of the four following options which encompass the VHA ORD educational requirements:
(a) The VHA Overview of Good Clinical Practice and Human Subjects Protection module **and** the PVAMC Education in the Protection of Human Research Participants training module and scoring at least 75% on the post-test.
(b) NCI Human Participants Protection Education for Research Teams education module, http://cme.nci.nih.gov/, the PVAMC Education in the Protection of Human Research Participants training module and scoring at least 75% on the post-test **and** the VHA GCP module.
(c) University of Rochester Medical Center's manual Protecting Study Volunteers in Research **and** post-test and the PVAMC Education in the Protection of Human Research Participants training module and scoring at least 75% on the post-test.

(d) University of Miami's Collaborative IRB Training Initiative web based training modules, 1-9 and 11-13, and receiving a total score of at least 75% on the post-test modules **and** the VHA GCP module
   i. Register for the CITI course by accessing the University of Miami CITI website at: http://www.miami.edu/bb/vareg/.
   ii. Complete and submit online the VA Registration Page.
   iii. Follow the instructions sent from the CITI program to the register's e-mail account, regarding accessing and beginning the CITI Training program. The training module may be done at separate intervals and will take approximately four to six hours to complete.
   iv. Once completed, follow the instructions indicated on the website for submitting the test results online.
   v. Submit the certificates of successful completion to the R&D Service Office upon receipt. Note: CITI will send an e-mail certificate to the e-mail account indicated when registering for the course.

(e) All of the education modules are available through the R&D Service website at: http://www.va.gov/portlandrd/pages/support/hrpp/training.htm. Submit the completion certificates to the RACC in the R&D Service Office.

b. **Principal Investigators**

Principal Investigators must adhere to the following procedures:

(1) Successfully fulfill the educational requirement in the protection of human research participants.
(2) As necessary, complete the above educational requirements prior to initial review of human research project submission to the IRB.
(3) Submit documentation of successful completion of educational requirements prior to initial review of research project submission to the IRB, if not previously completed.
(4) Alert the IRB to changes of study personnel.
(5) Ensure all required individuals involved in their studies have completed the above required protection of human research participants training.
(6) Complete the education requirement in the protection of human subjects in research training annually.

c. **New Employees**

New employees who handle identifiable VA patient human biological specimens, identifiable VA patient data, and/or have direct research related contact with VA patients participating in IRB approved research must adhere to the following procedures:

(1) Successfully fulfill the educational requirement in the protection of human research participants.
(2) Submit documentation of education in human subject protection to the Research Service Office upon successful completion and before they have contact with human subjects.
(3) Complete the protection of human subjects in research training annually.

d. **Individuals Not Required to Complete the Education Requirements**

(1) Members of the research team who are strictly administrative staff, e.g. receptionist, including any individuals that may have contact with a patient for scheduling purposes only.
(2) Individuals who are based at an affiliate or other outside institution, and who do not come to the VA or do not directly interact with VA research participants (This does not apply to individuals who have any type of appointment at the VA: they must complete the education requirements.)
(3) Co-investigators who do not work at the VA (e.g. a VA researcher may collaborate with researchers from outside the VA, but the VA portion of the study is conducted at the VA with

VA personnel. The outside people may be co-investigators on a VA study, and have their names listed on consent forms given to VA enrollees, but if the outside researchers do not come to the VA to perform the research or enroll VA patients, they are not required to complete these education requirements.

(4) Outside biostatisticians (e.g. VA researchers may send their data to an affiliate or other outside based statistician for processing).
(5) Outside lab technicians (e.g. VA researchers may send VA specimens to be processed at an affiliate or other outside lab.
(6) Volunteers from the community who serve on an IRB or R&D Committee.
(7) Members of groups like data safety monitoring boards (DSMB) who are recruited from non-VA institutions.
(8) Clinical personnel who periodically perform tests on research patients as part of their routine jobs (e.g. X-ray, nuclear medicine, or medical laboratory technologists who occasionally perform a test on a research patient as part of their routine clinical duties).
(9) Individuals working with de-identified VA patient data or de-identified VA patient human biological specimens.

5. REFERENCES:

VHA Directive 2003-036, July 7, 2003, Credentials and Training of Employees Involved in Human Subjects Research

Memorandum from the Deputy Under Secretary for Health for Operations and Management, May 19, 2003

National Committee for Quality Assurance Standards

6. CONCURRENCES: Endorsed by the R&D Committee 06/28/2004

7. RESCISSION: HRPP: Policy & Procedure No. 4, Endorsed by the R&D Committee 06/10/2002; 06/16/2003; 11/24/2003; and 05/03/2004

Department of Veterans Affairs, Office of Research & Development, memorandum dated March 14, 2001

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service